



Standoff Holder and Standoff Pad for Ultrasound Probe  
Serial Number: 10/695,988

Office Action) is clearly used on specialized ultrasound **probes 52** that are inserted into a body cavity (internally) such as the rectum or the vagina. The acoustic window on **probe 52 (in Fig. 2)** is located in the **middle section 56** on **probe 52** near one end. The acoustic window on **probe 52** is not located on the distal end of the **probe 52** but on the shaft (on the side) of **probe 52**.

The applicant's standoff holder is used to hold a standoff pad on probes that are placed on the external surface of the body (the skin surface, not internally or within a body cavity). The applicant's standoff holder is to be utilized by probes with acoustic windows that are located on the distal end of a probe and not on the shaft of a **probe 52** as discussed by Curtis.

Curtis's disclosure involves **sheath 50** (a probe cover for protection) that is used on **probe 52** that has the acoustic window on the side of **probe 52** and is used for an internal exam (i.e. a rectum) which is very different from the applicant's standoff holder, which is used to hold a standoff pad that covers an acoustic window on the distal end of a probe and then applied to an external body surface (i.e. the skin).

The applicants believe that the Curtis disclosure about a **sheath 50** (a protective cover) is not the same as a standoff holder which holds a standoff pad.

**Detailed Action : Examiner's Remark: Page 3 in regard to Claim 4, Curtis teaches plastic strips: Referring to Curtis –Col 4, Line 6.**

Applicant's response: In Fig. 2 of this Detailed Office Action (page 3) note "**Band 78**": It is stated in the specifications (Curtis, col 4, line 6) that Curtis teaches that **Band 78** is comprised of "latex", which is "elastic and flexible". **Band 78** has 2 functions according to Curtis. The first function of **Band 78** is to hold **Sheath 50** in place (stabilize **sheath**

50). The second function of **Band 78** is to apply compression to **sheath 50** which allows for the filling of a **chamber 118** (Fig. 4, US Patent 4,815,470;Curtis) within **sheath 50** with fluid or gel and this compression helps hold the fluid or gel within **chamber 118**.

(**Band 78** is just like a rubber band). Curtis does not teach of plastic strips that envelope a probe with two open ends that will function to hold an **ultrasound standoff pad**.

Curtis teaches about a **sheath 50** that is used to cover a **probe 52** this is inserted inside a body cavity like a rectum.

The applicants believe that the Curtis disclosure about protective **sheath 50** (a cover) is not the same as a standoff holder which holds a standoff pad.

**Detailed Action : EXAMINER'S REMARK: Page 3 in regard to Claims 5 & 6:**

**Referring to Figure 2 Curtis; elastic sock is round (claim 5), and elastic sock conforms to the shape of the probe because of its elastic nature (claim 6)**

Applicant's response: Curtis teaches of a **sheath 50** that is used to cover **probe 52** that is inserted inside a body cavity such as a rectum. This specialized **probe 52** is round and elongated so that it may be inserted into a body cavity. Curtis teaches that **sheath 50** is used as a protective device or cover for **probe 52**, and **sheath 50** is designed and shaped to fit elongated **probe 52**. Curtis does not teach of an elastic standoff holder which conforms to the exterior of different shaped probes that have an acoustic window on the distal end which is placed on the exterior surface of the body (i.e. the skin surface not in a body cavity such as the rectum). Nor Curtis does not teach that **sheath 50** could be placed on other shaped probes (i.e. square, flat rectangular or other) and accommodate the different shapes. Curtis teaches **probe 52** as depicted in FIG. 2 (And Figs. 3– 7).

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The applicants believe that the Curtis disclosure about **sheath 50** is not the same as a standoff holder which is used to hold a standoff pad.

**Remark to Detailed Action; EXAMINER'S REMARK: Page 3, No. 5 under 35**

**USC 102 (b)- Claims 1 – 12 anticipated by Oaks et al. (EP 0-527 651 A1)**

**NUMBER 5:**

**The examiners reference to claims 1, 7, 8, 10, and 12; as it relates to Column 4, line 10 (elastic properties) in Oaks disclosure (Oaks (EP 0 527 651 A1)**

Applicant's response: Oaks teaches in column 4, line 10, about a **body 22** (an acoustically transmissive material **defined in col. 3 line 44**) which is a standoff pad not the **retention clip 20**. It is the reference to **body 22** (the standoff pad) that Col.4, line 10 is describing as being soft rubber, polymetric materials... & gelatinous,... having the properties of a hydrogel which is inserted into **retention clip 20**. ( It is not the **retention clip 20** that is describe as having elastic properties)

**There is a typographical error in col 4, on line 4 were the body (22) is incorrectly numbered 20 (which is the retention clip 20 defined in col 3 line 39).**

The applicant's standoff holder is not a molded rigid material (as is **retention clip 20**) as describe by Oaks. The applicant's standoff holder is a flexible elastic sock that will accommodate and conform to all shapes and sizes of probes made by many different manufactures. Oaks **retention clip 20** as described would have to be custom molded and produced for each of the different shape and sizes of probes and customized for each probe manufacturer. **Retention clip 20** can not accommodate different shaped probes as describe by Oaks.

The applicants believe that the Oaks disclosure about a rigid **retention clip 20** custom molded for a specific probe (one) is self limiting and not the same as a flexible elastic

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sock standoff holder that accommodates a number of different sizes and shaped probes (many).

Oaks disclosure = One **retention clip 20** molded for each probe shape or size.

The applicants disclosure = one elastic standoff holder for many different size & shape probes.

Claims 8, 9, 11, and 12 have been removed from this application.

**.Detailed Action – Page 4**

**EXAMINER'S REMARKS: In regard to claim 2- Oaks teaches expansion ribs and axial ribs.**

Applicant's Response: Oaks speaks of four **bent tabs 26** which are part of **retention clip 20**. The purpose of the **four bent tabs 26** are used to "snap" **retention clip 20** on **scanhead 10**. Oaks teaches in col. 3 , line 50 that these **tabs 26** snap over the shoulder of **scanhead 10** holding **retention clip 20** in place.

The applicant's standoff holder does not have any **bent tabs 26**. Oaks **retention clip 20** along with **four bent tabs 26** are necessary to hold the device to **scanhead 10** due to the rigidity of the described **retention clip 20**. The applicant's standoff holder comprise a flexible sock having expansion ribs which eliminate the need of **bent tabs 26** to affix the standoff holder to **scanhead 10**.

The applicant's application describes a standoff holder that can accommodate any number of different types and different shaped **scanheads 10** unlike Oaks described **retention clip 20** which is custom molded for each and every different size and shaped **scanhead 10**.

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**EXAMINER'S REMARKS: In regards to claim 3 – Oaks teaches that the sock is made of rigid but somewhat flexible plastic.....**

Applicant's Response: Oaks teaches of a **retention clip 20** that is only flexible enough to snap onto **scanhead 10**. **Retention clip 20** is custom molded to fit on **scanhead 10** and would not attach to other shaped probes (i.e. oval or round). Unlike the applicant's standoff holder which accommodates a variety of shapes and sizes of probes, the rigidity and shape of the Oaks described, **retention clip 20** is self limiting and will only accommodate the probe it was designed for during the installing of and removing from **scanhead 10**.

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**EXAMINER'S REMARKS: In regards to claim 4- Oaks teaches plastic strips (col 4, line 6)**

Applicant's Response: Col 4, line 6; Oaks is referring to a standoff pad (**body 22**) and does not discuss plastic strips. The applicants have already discussed the **four bend plastic tabs 26** above and the typographical error found in this area of the Oaks specification.

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**EXAMINER'S REMARKS: In regards to claim 5 - Oak's teaches a sock is round- (Fig. 2 on page 3 of the detailed office action.)**

Applicant's Response: Oaks does not describe or disclose any sock, round or otherwise. Fig. 2 on page 2 of the detailed office action refers to Curtis (US- Patent 4,815,470) not Oaks (EP 0 527 651 A1). The Curtis round **sheath 50** protective cover was addressed above under- Detailed Action : Page 3 in regard to Claims 5 & 6: Referring to Fig. 2.

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**EXAMINER'S REMARKS:** In regards to claim 6, Oak's elastic sock inherently conforms to the shape of the probe because of its elastic nature.

Applicant's Response: Oaks does not describe or disclose any sock, round or otherwise.

Oak's disclosure describes a **retention clip 20** that is custom molded and rigid. The amount of flexibility afforded by custom molded **retention clip 20** is enough to just snap over the edge of **scanhead 10** that is was designed for.

The applicant's elastic standoff holder as disclosed, unlike Oaks, can accommodate a number of different sizes and shaped probes.

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**EXAMINER'S RESPONSE:** In regards to claim 9, Oaks teaches that the probe includes an acoustic window.

Applicant's Response: Claim 9 has been removed from the application.

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**EXAMINER'S RESPONSE:** In regards to claim 11, Oaks teaches all the structures of the claimed subject matter as to the cutting, tracing, marking, etc from gel pads.

Applicant's Response: Claim 11 has been remove from the application.

APPLICANTS SUMMARY:

Curtis discloses a probe **sheath 50** (a cover) that is used on specialized probes for examining body cavities, not a standoff holder which holds a standoff pad like the applicants.

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Oaks discloses a rigid **retention clip 20** that holds a standoff pad that is molded for specific shaped probes. Oaks **retention clip 20** is expensive because each probe will need to have a specific mold made to produce the different **retention clips 20** for different size and shaped probes. Oaks disclosure of his **retention clip 20** reveals the lack or the ability to expand to accommodate and conform to various probe shapes (round, square, oval etc) and or to adjust to various sizes of probes (small, medium, large, thick, thin, etc. Please see attached drawings of probes with distal acoustic windows shown in various sizes shapes and sizes.) Oaks would have to make 6 different **retention clips 20**. A mold for each **retention clip 20** would have to be designed and manufactured for each size and shape probe in this example. The applicant's accommodative standoff holder would fit all examples.

Oaks disclosure = One **retention clip 20** per probe.

The applicants disclosure = One elastic standoff holder for many different probes.

The applicants disclose an accommodative standoff holder comprising elastic sock which fits numerous shapes and sizes of probes.

Neither Oaks nor Curtis teach about therapeutic ultrasound. Therapeutic probes also vary in size and shape. The applicant's disclosure can accommodate and function on various size and shaped therapeutic ultrasound probes.

#### AMENDMENTS:

##### **Specification:**

**Page 10- line 8** Remove "holder10" and change to "holder 10" (space added between holder and 10)

**Page 14- line 3** Remove "sock12" and change to "sock 12" (space added between sock and 12)